IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS

MARY BOUTTE;	§	
ALICE BURTLE;	§	
RALEIGH CARR;	§	
EDWIN L. CUNNIFF;	§	**JURY DEMAND**
CHARLENE H. DOUSE;	§	
VALENTIN ORTEGA;	§	
CHARLES PILGRIM;	§	
JOE M. TAYLOR, JR.;	§	**Civil Action No. 4:09-cv-3588**
ERIC A. BARBEE, Individually and on Behalf of the Estate of FREDERICK BARBEE;	§	
BESSIE BOOKER, Individually and on Behalf of the Estate of MARY L. BOOKER;	§	
LAVONIA BRADLEY, Individually and on Behalf of the Estate of ALFONSIA BRADLEY;	§	
MERLIN BROWN, Individually and as Representative of the Estate of MORRIS O. BROWN;	§	
ANNIE H. BUSTLE, Individually and as Representative of the Estate of WILLIAM A. BUSTLE;	§	
BRENDA GREMLI, Individually and on Behalf of the Estate of BONNIE CHENOWETH;	§	
PAUL COCKROFT, Individually and on Behalf of the Estate of GILBERT J. COCKROFT;	§	
HATTIE SCOTT, Individually and on Behalf of the Estate of HATTIE SCOTT; and	§	
JOSEPH HERNDON, Individually and on Behalf of the Estate of ELNORA HERNDON.	§	
	§	
Plaintiffs,	§	

BAYER CORPORATION, BAYER HEALTHCARE PHARMACEUTICALS, INC. (As Successor in Interest of Bayer Pharmaceuticals Corporation), and BAYER SCHERING PHARMA AG

Defendants.

COMPLAINT AND DEMAND FOR JURY TRIAL

COME NOW PLAINTIFFS, **MARY BOUTTE; ALICE BURTLE; RALEIGH CARR; EDWIN L. CUNNIFF; CHARLENE H. DOUSE; VALENTIN ORTEGA; CHARLES PILGRIM; JOE M. TAYLOR, JR.; ERIC A. BARBEE, Individually and on Behalf of the Estate of FREDERICK BARBEE; BESSIE BOOKER, Individually and on Behalf of the Estate of MARY L. BOOKER; LAVONIA BRADLEY, Individually and on Behalf of the Estate of ALFONSIA BRADLEY; MERLIN BROWN, Individually and as Representative of the Estate of MORRIS O. BROWN; ANNIE H. BUSTLE, Individually and as Representative of the Estate of WILLIAM A. BUSTLE; BRENDA GREMLI, Individually and on Behalf of the Estate of BONNIE CHENOWETH; PAUL COCKROFT, Individually and on Behalf of the Estate of GILBERT J. COCKROFT; HATTIE SCOTT, Individually and on Behalf of the Estate of HATTIE SCOTT; and JOSEPH HERNDON, Individually and on Behalf of the Estate of ELNORA HERNDON.,** by and through counsel, and files this Complaint seeking judgment against Defendants **BAYER CORPORATION, a Division of Bayer A.G.; BAYER HEALTHCARE, a Division of Bayer Pharmaceuticals Corporation; BAYER SCHERING PHARMA A.G., a Foreign Corporation** and in support thereof states as follows:

I. Statement of Jurisdiction

1. This Honorable Court has jurisdiction over this cause pursuant to 28 U.S.C. §1332 because there is complete diversity between Plaintiffs and Defendants and the matter in controversy greatly exceeds the sum of seventy-five thousand dollars ($75,000.00), exclusive of interest and costs.

II. Venue

2. Venue is proper in the Southern District of Texas pursuant to 28 U.S.C. §1391(a)(3) and 28 U.S.C. §1391(b)(3) and 28 U.S.C. §(c). Defendants are subject to personal jurisdiction in the Southern District of Texas; one or more Defendants may be found in the Southern District of Texas and all Defendants are corporations conducting business by selling and distributing its products in the Southern District of Texas.

III. Parties

3. Plaintiffs are as follows:

a. Plaintiff MARY BOUTTE is a citizen of the State of Texas. Plaintiff brings this civil action for the injuries she suffered as a direct result of her use of Trasylol. In December 2006, Plaintiff MARY BOUTTE, underwent coronary artery bypass surgery in the State of Texas and suffered injuries from the administration of Trasylol, specifically renal dysfunction and injury.

b. Plaintiff ALICE BURTLE is a citizen of the State of Illinois. Plaintiff brings this civil action for the injuries she suffered as a direct result of her use of Trasylol. In July 2005, Plaintiff ALICE BURTLE, underwent coronary artery bypass surgery in the State of Illinois and suffered injuries from the administration of Trasylol, specifically renal dysfunction and injury.

c. Plaintiff RALEIGH CARR is a citizen of the State of Kentucky. Plaintiff brings this civil action for the injuries he suffered as a direct result of his use of Trasylol. In June 1999, Plaintiff RALEIGH CARR, underwent coronary artery bypass surgery in the State of Kentucky and suffered injuries from the administration of Trasylol, specifically renal dysfunction and injury.

d. Plaintiff CHARLENE H. DOUSE is a citizen of the State of Louisiana. Plaintiff brings this civil action for the injuries she suffered as a direct result of her use of Trasylol. In October 2002, Plaintiff CHARLENE H. DOUSE, underwent coronary artery bypass surgery in the State of Louisiana and suffered injuries from the administration of Trasylol, specifically renal dysfunction and injury.

e. Plaintiff EDWIN L. CUNNIFF is a citizen of the State of Missouri. Plaintiff brings this civil action for the injuries he suffered as a direct result of his use of Trasylol. In June 2007, Plaintiff EDWIN L. CUNNIFF, underwent coronary artery bypass surgery in the State of Missouri and suffered injuries from the administration of Trasylol, specifically heart attack.

f. Plaintiff VALENTIN ORTEGA is a citizen of the State of Texas. Plaintiff brings this civil action for the injuries he suffered as a direct result of his use of Trasylol. In January 2004, Plaintiff VALENTIN ORTEGA, underwent coronary artery bypass surgery in the State of Texas and suffered injuries from the administration of Trasylol, specifically renal dysfunction and injury.

g. Plaintiff CHARLES PILGRIM is a citizen of the State of South Carolina. Plaintiff brings this civil action for the injuries he suffered as a direct result of his use of Trasylol. On or about May 13, 2005, Plaintiff CHARLES PILGRIM, underwent

coronary artery bypass surgery in the State of South Carolina and suffered injuries from the administration of Trasylol, specifically renal dysfunction and injury.

h. Plaintiff JOE M. TAYLOR, JR. is a citizen of the State of Texas. Plaintiff brings this civil action for the injuries he suffered as a direct result of his use of Trasylol. In June 2005, Plaintiff JOE M. TAYLOR, JR, underwent coronary artery bypass surgery in the State of Texas and suffered injuries from the administration of Trasylol, specifically renal dysfunction and injury.

i. Plaintiff FREDERICK BARBEE, Deceased, was a citizen of the State of Ohio. Plaintiff brings this civil action for the injuries he suffered as a direct result of her use of Trasylol. In January 2002, Plaintiff FREDERICK BARBEE, underwent coronary artery bypass surgery in the State of Ohio and suffered injuries from the administration of Trasylol, specifically renal dysfunction and injury.

j. Plaintiff ERIC A. BARBEE is a citizen of the State of Ohio. Plaintiff brings this civil action for the injuries he suffered and on Behalf of the Estate of FREDERICK BARBEE.

k. Plaintiff MARY L. BOOKER, Deceased, was a citizen of the State of Illinois. Plaintiff brings this civil action for the injuries he suffered as a direct result of her use of Trasylol. In December 2007, Plaintiff MARY L. BOOKER, underwent coronary artery bypass surgery in the State of Illinois and suffered injuries from the administration of Trasylol, specifically renal dysfunction and injury.

l. Plaintiff BESSIE BOOKER is a citizen of the State of Illinois. Plaintiff brings this civil action for the injuries she suffered and on Behalf of the Estate of MARY L. BOOKER.

m. Plaintiff ALFONZIA BRADLEY, Deceased, was a citizen of the State of Nebraska. Plaintiff brings this civil action for the injuries she suffered as a direct

result of her use of Trasylol. In June 2004 Plaintiff ALFONZIA BRADLEY, underwent coronary artery bypass surgery in the State of Nebraska and suffered injuries from the administration of Trasylol, specifically renal dysfunction and injury.

n. Plaintiff LABONIA BRADLEY is a citizen of the State of Nebraska. Plaintiff brings this civil action for the injuries she suffered and on Behalf of the Estate of ALFONZIA BRADLEY.

o. Plaintiff MORRIS O. BROWN, Deceased, was a citizen of the State of New York. Plaintiff brings this civil action for the injuries he suffered as a direct result of his use of Trasylol. In February 1994, Plaintiff MORRIS O. BROWN, underwent coronary artery bypass surgery in the State of New York and suffered injuries from the administration of Trasylol, specifically renal dysfunction and injury and stroke.

p. Plaintiff MERLIN BROWN is a citizen of the State of New York. Plaintiff brings this civil action for the injuries she suffered and on Behalf of the Estate of MORRIS O. BROWN.

q. Plaintiff WILLIAM A. BUSTLE, Deceased, was a citizen of the State of North Carolina. Plaintiff brings this civil action for the injuries he suffered as a direct result of his use of Trasylol. In September 2003, Plaintiff WILLIAM A. BUSTLE, underwent coronary artery bypass surgery in the State of North Carolina and suffered injuries from the administration of Trasylol, specifically renal dysfunction and injury.

r. Plaintiff ANNIE H. BUSTLE is a citizen of the State of North Carolina. Plaintiff brings this civil action for the injuries she suffered and on Behalf of the Estate of WILLIAM A. BUSTLE.

s. Plaintiff BONNIE CHENOWETH, Deceased, was a citizen of the State of Illinois. Plaintiff brings this civil action for the injuries she suffered as a direct result of her use of Trasylol. In July 2003, Plaintiff BONNIE CHENOWETH, underwent coronary artery bypass surgery in the State of Illinois and suffered injuries from the administration of Trasylol, specifically renal dysfunction and injury.

t. Plaintiff BRENDA GREMLI is a citizen of the State of Illinois. Plaintiff brings this civil action for the injuries she suffered and on Behalf of the Estate of BONNIE CHENOWETH.

u. Plaintiff GILBERT J. COCKROFT, Deceased, was a citizen of the State of Wisconsin. Plaintiff brings this civil action for the injuries he suffered as a direct result of her use of Trasylol. On or about March 27, 2001, Plaintiff GILBERT J. COCKROFT, underwent coronary artery bypass surgery in the State of Wisconsin and suffered injuries from the administration of Trasylol, specifically renal dysfunction and injury and heart attack

v. Plaintiff PAUL COCKROFT is a citizen of the State of Wisconsin. Plaintiff brings this civil action for the injuries she suffered and on Behalf of the Estate of GILBERT J. COCKROFT.

w. Plaintiff IRENE HOPSON, Deceased, was a citizen of the State of Mississippi. Plaintiff brings this civil action for the injuries she suffered as a direct result of her use of Trasylol. On or about June 26, 2007, Plaintiff IRENE HOPSON,

underwent coronary artery bypass surgery in the State of Mississippi and suffered injuries from the administration of Trasylol, specifically renal dysfunction and injury.

x. Plaintiff HATTIE SCOTT is a citizen of the State of Mississippi. Plaintiff brings this civil action for the injuries she suffered and on Behalf of the Estate of IRENE HOPSON.

y. Plaintiff ELNORA HERNDON, Deceased, was a citizen of the State of Ohio. Plaintiff brings this civil action for the injuries she suffered as a direct result of her use of Trasylol. On or about September 29, 2007, Plaintiff ELNORA HERNDON, underwent coronary artery bypass surgery in the State of Ohio and suffered injuries from the administration of Trasylol, specifically renal dysfunction and injury.

z. Plaintiff JOSEPH HERNDON is a citizen of the State of Ohio. Plaintiff brings this civil action for the injuries she suffered and on Behalf of the Estate of ELNORA HERNDON.

4. Defendant BAYER CORPORATION, is a corporation formed in the State of Indiana with its principal place of business located at 100 Bayer Road, Pittsburgh, Pennsylvania 15205. At all times material to this lawsuit, Bayer was engaged in the business of developing, manufacturing, licensing, promoting, marketing, distributing, testing, warranting and/or selling in interstate commerce and the State of Connecticut, either directly or indirectly, the pharmaceutical Trasylol, also known as Aprotinin. BAYER CORPORATION may be served by delivering a copy of this complaint and summons to its agent for service in Texas, Corporation Service Company d/b/a CSC-Lawyers Incorporating Service, 701 Brazos Street, Suite 1050, Austin, Texas 78701.

5. Defendant BAYER HEALTHCARE PHARMACEUTICALS INC., as successor in interest of BAYER PHARMACEUTICALS CORPORATION, is a wholly owned subsidiary of Defendant Bayer Corporation, incorporated in the state of Delaware, with its principal place of business located in Wayne, New Jersey. BAYER HEALTHCARE PHARMACEUTICALS INC. may be served by delivering a copy of this complaint and summons to its agent for service in Texas, Corporation Service Company d/b/a CSC-Lawyers Incorporating Service, 701 Brazos Street, Suite 1050, Austin, Texas 78701.

6. Defendant BAYER SHERING PHARMA A.G., a healthcare and medical products company, is a German corporation with its principal place of business in Leverkusen, Germany. Service on Bayer SHERING PHARMA A.G. is being performed pursuant to the Hague Convention on service abroad. At all times relevant herein, Bayer HealthCare A.G. was in the business of designing, testing, manufacturing, distributing and promoting certain pharmaceutical products, including Trasylol.

7. Hereinafter, Bayer Corporation, Bayer Healthcare Pharmaceuticals Inc. and Bayer Schering Pharma AG may be referred to individually and/or collectively as "Bayer" or "Defendants."

IV. Facts

8. Plaintiffs hereby adopt and incorporate by reference all the above allegations and further states as follows:

History of Trasylol

9. Trasylol (also known as Aprotinin injection) is a naturally occurring proteolytic enzyme inhibitor obtained from bovine lung. Aprotinin consists of 58 amino acid residues. It is a single-chain polypeptide, consisting of 6512 daltons and is cross-linked by three disulfide bridges. The

reactive bond site for Aprotinin is lysine – 15 – alanine – 16, and it forms reversible stoichiometric complexes.

10. Aprotinin was discovered in the 1930s when Kraut et al. isolated a kallikerin inhibitor from bovine lung.

11. On information and belief, Aprotinin has been sold outside the United States since the 1950's as Trasylol, a medicine used in the treatment of acute pancreatitis.

12. Trasylol was first sold in the United States in 1993 to control bleeding in coronary artery bypass graft surgery. It is supplied as a clear, colorless, sterile isotonic solution for intravenous administration.

13. Trasylol is indicated for prophylactic use to reduce peri-operative blood loss and the need for blood transfusion in patients undergoing cardiopulmonary bypass in the course of coronary artery bypass graft surgery.

14. Trasylol is a broad spectrum protease inhibitor, which modulates the systemic inflammatory response associated with cardiopulmonary bypass surgery. The effects of Trasylol use in cardiopulmonary bypass surgery involve a reduction in inflammatory response, which may decrease the need for blood transfusions.

15. Trasylol inhibits pro-inflammatory cytokine release and maintains glycoprotein homeostasis.

16. According to Bayer, since its approval, an estimated 4.3 million patients have been given Trasylol.

17. Bayer estimated that Trasylol sales generated about $293 million in 2005 alone, making it the company's 11th largest-selling drug.

18. In late 2005, Bayer forecast that Trasylol would someday generate upwards of $600 million annually.

19. On January 26, 2006, *The New England Journal of Medicine (NEJM)* published an article by Mangano et al. reporting an association of Trasylol with, among other things, serious renal toxicity in patients undergoing coronary artery bypass grafting surgery. This study was an observational study of patients who received either Trasylol, one of two alternative drugs intended to decrease peri-operative bleeding (aminocaproic acid or tranexamic acid), or no specific drug treatment.

20. On December 15, 2006, the U.S. Food and Drug Administration (FDA) sent an Alert to healthcare professionals advising of a change in the product label for Trasylol:

> The new labeling for Trasylol (December 2006) has a more focused indication for use, a new Warning about renal dysfunction, a revised Warning about anaphylactic reactions, and a new Contraindication. Trasylol is now indicated only for prophylactic use to reduce peri-operative blood loss and the need for blood transfusion in patients who are at *an increased risk for blood loss and blood transfusion* undergoing cardiopulmonary bypass in the course of coronary artery bypass grafting (CABG) surgery. Trasylol should be administered only in the operative setting where cardiopulmonary bypass can be started quickly. Trasylol should not be administered to any patient with a known or suspected exposure to Aprotinin within the past 12 months.

21. As of December 2006, the Defendants revised the label for Trasylol to include a specific statement in the WARNING section of the label that use of Trasylol creates an increased risk of renal dysfunction and renal failure.

22. In October 2007, Bayer was notified that the Executive Committee of a Canadian-based clinical study of Trasylol in high-risk cardiac surgery patients, known as the BART trial, had halted the study. This followed a letter from the BART Data Safety Monitoring Board informing the Committee that a planned periodic data analysis indicated an increase in all-cause mortality

(that almost reached conventional statistical significance for 30-day mortality) for patients in the Trasylol treatment arm compared to patients who received the alternative drug products aminocaproic acid or tranexamic acid.

23. On or about November 5, 2007, the FDA asked Defendants to discontinue the sale of Trasylol in the United States. According to the FDA, "it is not possible to determine and identify a population of patients undergoing cardiac surgery for which the benefits of Trasylol outweigh the risks."

24. With no contributory negligence on their part, Plaintiffs were administered Trasylol, a pharmaceutical product designed, manufactured, promoted, distributed and sold by Defendants.

25. As a direct, proximate, and legal result of the negligence, carelessness, and other wrongdoing of the Defendants, as described herein, Plaintiffs experienced renal insufficiency soon after heart surgery, subsequently went into renal failure, other organ complications, resulting in death. In addition, as a direct, proximate, and legal result of the negligence, carelessness, and other wrongdoing of the Defendants Plaintiffs suffered strokes and cardiac events.

26. As a direct, proximate, and legal result of the negligence, carelessness, and other wrongdoing of the Defendants, as described herein, Plaintiffs were forced to undergo painful and debilitating medical treatments.

27. As a direct, proximate, and legal result of the negligence, carelessness, and other wrongdoing of the Defendants, as described herein, Plaintiffs sustained permanent and devastating injuries, including but not limited to, renal failure, other organ failure, and death. In addition, as a direct, proximate, and legal result of the negligence, carelessness, and other wrongdoing of the Defendants Plaintiffs suffered strokes and cardiac events.

28. All of said injuries caused Plaintiffs extensive anxiety, distress, fear, pain, suffering, and depression, while they substantially reduced her ability to enjoy life, and ultimately resulted in their death.

COUNT ONE –- STRICT LIABILITY

29. Plaintiffs hereby adopt and incorporates by reference all the above allegations and further states as follows:

30. Defendants are liable to Plaintiffs for the injuries and damages sustained by Plaintiffs due to the defective design and/or formulation of Trasylol.

31. At all times material to this lawsuit, Defendants manufactured Trasylol.

32. At all times material to this lawsuit, Defendants were engaged in the business of distributing and selling Trasylol.

33. Defendants sold Trasylol, which was administered to Plaintiffs during surgery, as alleged in this Complaint.

34. The Trasylol administered to Plaintiffs was defective in design or formulation in that, when it left the hands of the Defendants, this drug was unreasonably dangerous to the extent beyond that which could reasonably be contemplated by Plaintiffs or their physicians, and any benefit of this drug was outweighed by the serious and undisclosed risks of its use when prescribed and used as the Defendants intended.

35. The Trasylol administered to Plaintiffs was defective because there is no patient for whom the benefits of Trasylol outweigh the risks.

36. The Trasylol administered to Plaintiffs was defective at the time it was distributed by the Defendants or left their control.

37. The Trasylol administered to Plaintiffs was expected to reach the user without substantial change in the condition in which it was sold.

38. The Trasylol administered to Plaintiffs reached them without substantial change in the condition in which it was sold.

39. Plaintiffs were patients whom the Defendant reasonably expected to use Trasylol.

40. The defects in the Trasylol administered to Plaintiffs were a direct and proximate cause of the injuries and death, and damages sustained by Plaintiffs as set forth in this Complaint.

41. Defendants were entitled to withdrawn Trasylol from the market at any time, even if the FDA disagreed with that decision.

COUNT TWO – NEGLIGENCE

42. Plaintiffs hereby adopt and incorporate by reference all the above allegations and further states as follows:

43. Defendants are liable to Plaintiffs for the negligent development, study, manufacture, distribution and sale of the unreasonably dangerous product Trasylol.

44. At all times relevant to this lawsuit, Defendants owed a duty to consumers, including Plaintiffs and their health care providers to assess, manage, and communicate the risks, dangers, and adverse effects of Trasylol and to suspend distribution and sale of Trasylol when Defendants discovered it to be unreasonably dangerous.

45. Defendants' duties included, but were not limited to, carefully and properly designing, testing, manufacturing, promoting, selling, and/or distributing Trasylol into the stream of commerce, and providing information and warnings with regard to this drug.

46. Defendants negligently and carelessly breached the above-described duties to Plaintiffs by committing negligent acts and/or omissions including, but not limited to, the following:

(A) Defendants failed to use ordinary care in designing, testing, and manufacturing Trasylol so as to reveal and communicate the high risk to users of unreasonable, dangerous side-effects, some of which are fatal, such as renal failure, heart attack and stroke;

(B) Defendants failed to accompany Trasylol with adequate information that would alert doctors, consumers, and other users to the potential adverse side effects associated with the use of these drugs and the nature, severity and duration of such adverse effects;

(C) Defendants failed to conduct adequate pre-clinical testing and post-marketing surveillance to determine and communicate the safety profile and side effects of Trasylol;

(D) Defendants failed to warn Plaintiffs or their physicians prior to actively encouraging the sale of Trasylol, either directly or indirectly, orally or in writing, about the possibility of renal failure and injury as a result of the use of this drug, as well as the possibility of heart attack and strokes;

(E) Defendants continued to promote the safety of Trasylol, while downplaying any risks, even after Defendants knew or should have known of the risks of Trasylol;

(F) Defendants knew or should have known that the use of Trasylol involved a risk of kidney failure, and renal injury and/or that Trasylol was unreasonably dangerous, involved risks of heart attack and strokes, and failed to communicate that information to Plaintiffs and their physicians;

(G) At the time of Plaintiffs surgeries, Defendants had or should have had bona fide scientific data which indicated an association between the use of Trasylol and the

a risk of kidney failure, renal injury, death, stroke, and cardiac events and could have distributed that information to Plaintiffs and their physicians even if that information was not included in the FDA-approved product labeling;

(H) Defendants failed to provide consumers, like Plaintiffs, and their health care providers with bona fide scientific data which indicated that Trasylol was unreasonably dangerous, that there were no patients in whom the benefits of Trasylol outweighed the risks, and failed to promptly withdraw Trasylol from the market; and

(I) Defendants were otherwise careless or negligent.

47. Although Defendants knew or should have known that Trasylol caused unreasonably dangerous side effects which many users would be unable to remedy by any means, Defendants continued to market this drug to doctors for use in cardiac surgeries, when there were safer and less expensive alternatives available.

48. Defendants knew or should have known that consumers, like Plaintiffs, would suffer injury and death as a result of Defendants' failure to exercise ordinary care, as described above.

49. As a direct and proximate cause of Defendants' negligent acts and/or omissions, Plaintiffs suffered injuries, death, and damages, as set forth in this Complaint.

50. Defendants were entitled to provide consumers like Plaintiffs and their health care providers with bona fide scientific data which indicated an association between the use of Trasylol and the a risk of kidney failure, renal injury, heart attack, stroke and death and could have distributed that information to Plaintiffs and their physicians even if that information was not included in the FDA-approved product labeling. Defendants were entitled to provide consumers, like Plaintiffs, and their health care providers with bona fide scientific data which

indicated that Trasylol was unreasonably dangerous, that there were no patients in whom the benefits of Trasylol outweighed the risks, or could have withdrawn Trasylol from the market at any time, even if the FDA disagreed with that decision.

COUNT THREE – FRAUD AND MISREPRESENTATION

51. Plaintiffs hereby adopt and incorporates by reference all the above allegations and further states as follows:

52. Defendants are liable to Plaintiffs for innocent, negligent and/or willful misrepresentations regarding the safety, efficacy, and risk/benefit ratio of Trasylol to Plaintiffs and to the health care providers that prescribed, recommended, ordered, and dispensed Trasylol to her.

53. Through their actions and omissions in advertising, promoting, and otherwise, Defendants fraudulently, intentionally and/or negligently made public misrepresentations of material facts to, and/or concealed material facts from physicians and consumers like Plaintiffs, concerning the character and safety of Trasylol.

54. Defendants were entitled to provide consumers, like Plaintiffs, and their health care providers with bona fide scientific data which indicated an association between the use of Trasylol and the a risk of kidney failure, renal injury, heart attack, stroke and death and could have distributed that information to Plaintiffs and their physicians even if that information was not included in the FDA-approved product labeling. Defendants were entitled to provide consumers, like Plaintiffs, and their health care providers with bona fide scientific data which indicated that Trasylol was unreasonably dangerous, that there were no patients in whom the benefits of Trasylol outweighed the risks, or could have withdrawn Trasylol from the market at any time, even if the FDA disagreed with that decision.

55. Those public misrepresentations and omissions include, but are not limited to, those set forth in the general allegations section of this Complaint. Those misrepresentations and omissions further include, but are not limited to, the following:

(A) Defendants failed to disclose that pre-clinical and clinical testing and post-marketing surveillance was inadequate to determine the safety and side effects of Trasylol;

(B) Defendants failed to timely disclose, and/or intentionally concealed, data showing that Trasylol use dramatically increased the risk for renal failure, heart attack and stroke;

(C) Defendants failed to include adequate warnings with Trasylol about the potential and actual risks, and nature, scope, severity, and duration of any serious side effects of this drug, including without limitation, the risk of renal failure, heart attack, stroke, and death; and

(D) Defendants concealed and continue to conceal past and present facts – including that as early as the mid-nineties Defendants were aware of and concealed their knowledge of an association between the use of Trasylol and dangerous side effects, including renal failure, heart attack, stroke and death – from the consuming public, including Plaintiffs, when it had a duty to disclose.

56. Defendants' above-described acts and/or omissions were performed willfully, intentionally, and with reckless disregard for Plaintiffs and the public.

57. Defendants knew or should have known that these representations were false and that Plaintiffs and their physicians would rely on them. Defendants were obligated to disclose the foregoing risks, but failed to adequately and timely do so even after they were in possession of

information concerning those risks. Defendants' representations that Trasylol was safe for its intended use were false, since this drug was, in fact, unreasonably dangerous to the health of Plaintiffs when used during cardiac surgery, and there were alternative products available that were less expensive, effective and posed less risk.

58. In the alternative, Defendants failed to exercise reasonable care in ascertaining the accuracy of the information regarding the safe use of Trasylol and communicating that information to Plaintiffs and their physicians.

59. At the time of Defendants' fraudulent misrepresentations and active concealment, Plaintiffs was not aware of the falsity of the foregoing representations, nor were they aware that material facts concerning Trasylol had been concealed or omitted. In reliance upon Defendants' misrepresentations, Plaintiff's physicians were induced to and did order Trasylol to be administered to their during heart surgery.

60. Defendants were entitled to provide consumers, like Plaintiffs, and their health care providers with bona fide scientific data which indicated an association between the use of Trasylol and the a risk of kidney failure, renal injury, heart attack, stroke and death and could have distributed that information to Plaintiffs and their physicians even if that information was not included in the FDA-approved product labeling. Defendants were entitled to provide consumers, like Plaintiffs, and their health care providers with bona fide scientific data which indicated that Trasylol was unreasonably dangerous, that there were no patients in whom the benefits of Trasylol outweighed the risks, or could have withdrawn Trasylol from the market at any time, even if the FDA disagreed with that decision.

61. If Plaintiffs and their physicians had known the true facts concerning the risks of the use of Trasylol, in particular the risk of renal failure heart attack, stroke and death, they would not have used Trasylol and would have used one of the safer alternatives.

62. If Plaintiffs physicians had known the true facts concerning the risks of the use of Trasylol, in particular the risk of renal failure, heart attack, stroke and death, the physicians would not have administered Trasylol during surgery and would have administered one of the safe alternatives.

63. The reliance of Plaintiffs and their physicians upon Defendants' misrepresentations was justified, among other reasons, because said misrepresentations and omissions were made by individuals and entities who were in a position to know the true facts concerning Trasylol, while Ms. Bryant and her physicians were not in a position to know the true facts, and because Defendants overstated the benefits and safety of Trasylol and concomitantly downplayed the risks in its use, thereby inducing Plaintiffs physicians to use Trasylol in lieu of other, safer alternatives. At all times relevant hereto, Defendants' corporate officers, directors and/or managing agents knew or should have known of and ratified the acts of Defendants, as alleged herein.

64. As a direct and proximate result of the reliance of Plaintiffs and their physicians on Defendants' misrepresentations and concealment concerning the risks and benefits of Trasylol, Plaintiffs suffered injuries and damages and death, as set forth in this Complaint.

COUNT FOUR – EXPRESS WARRANTIES

65. Plaintiffs hereby adopt and incorporate by reference all the above allegations and further states as follows:

66. Trasylol was designed, tested, manufactured, distributed, promoted and sold by the Defendants; and was expected to, and did, reach Plaintiffs without a substantial change in its condition.

67. Defendants, through their advertising and promotional materials and the statements of sales representatives and paid endorsers, expressly warranted that Trasylol was safe for the use for which it was intended.

68. Defendants breached said express warranties in that Trasylol was unsafe in light of the risk of life-threatening side effects associated with its use, including, but not limited to, renal failure, heart attack, stroke and death.

69. Plaintiffs and their physicians relied to their detriment on Defendants' express warranties.

70. As a direct and proximate result of Defendants' breach of express warranties, Plaintiffs suffered injuries and damages, as set forth in this Complaint.

COUNT FIVE – IMPLIED WARRANTIES

71. Plaintiffs hereby adopt and incorporate by reference all the above allegations and further states as follows:

72. Trasylol was designed, tested, manufactured, distributed, promoted and sold by the Defendants; and was expected to, and did, reach Plaintiffs without a substantial change in its condition.

73. Defendants, through advertising and promotional materials and the statements of sales representatives and paid endorsers, impliedly warranted that Trasylol was safe for the use for which it was intended.

74. Defendants breached said implied warranties in that Trasylol was unsafe in light of the risk of life-threatening side effects associated with its use, including, but not limited to, renal failure, heart attack, and stroke.

75. Plaintiffs and their physicians relied to their detriment on Defendants' implied warranties.

76. As a direct and proximate result of Defendants' breach of implied warranties, Plaintiffs suffered injuries and damages, as set forth in this Complaint.

COUNT SIX – PUNITIVE DAMAGES

77. Plaintiffs hereby adopts and incorporates by reference all the above allegations and further states as follows:

78. Plaintiffs are entitled to punitive damages because Defendants' actions were reckless and without regard for the public's safety and welfare. Defendants misled both the medical community and the public at large, including Plaintiffs and their physicians, by making false representations about and concealing pertinent information regarding Trasylol. Defendants downplayed, understated and disregarded its knowledge of the serious and permanent side effects associated with the use of Trasylol, including renal failure, heart attack, stroke and death, despite information demonstrating the product was unreasonably dangerous.

79. The conduct of the Defendants in designing, testing, manufacturing, promoting, advertising, selling, marketing, and distributing Trasylol, and in failing to warn Plaintiffs and other members of the public of the dangers inherent in the use of Trasylol, which were known to the Defendants, was attended by circumstances of fraud, malice, or willful and wanton conduct, done heedlessly and recklessly, without regard to consequences, or of the rights and safety of others, including Plaintiffs.

80. At all times material hereto, Defendants had a duty to exercise reasonable care in the design, manufacture, testing, research and development, processing, advertising, marketing, labeling, packaging, distribution, promotion and sale of Trasylol.

81. Defendants breached their duty and were wanton and reckless in their actions, misrepresentations, and omissions toward the public generally, and Plaintiffs specifically, in the following ways:

(A) Upon information and belief, Defendants actually knew of Trasylol's defective nature, as set forth herein, but continued to design, manufacture, market, and sell Trasylol so as to maximize sales and profits at the expense of the health and safety of the consuming public, including Plaintiffs, and in conscious disregard of the foreseeable harm caused by Trasylol;

(B) Defendants spent millions of dollars a year researching and developing medicines and aggressively marketing Trasylol, but devoted far less attention to conducting sufficient pre-clinical testing, clinical testing, comparison testing, and adequate post-marketing surveillance of this drug; and

(C) Defendants continued to promote the safety of Trasylol, while providing no warnings at all about the unreasonable risk to consumers of death, kidney failure, congestive heart failure, and stroke associated with it, even after Defendants knew of that risk from multiple studies.

82. Defendants knew that Trasylol had unreasonably dangerous risks and caused serious side effects of which Plaintiffs and their physicians would not be aware. Defendants nevertheless advertised, marketed, distributed, and sold the medicine knowing that there were safer methods and products available.

83. Defendants' above-described actions were performed willfully, intentionally, and with reckless disregard for the rights of Plaintiffs and the public.

84. One or more of the aforesaid violations by Defendants were committed by Defendants with reckless disregard for the safety of the public and of Plaintiffs as a product user.

85. One or more of the aforesaid violations by Defendants were committed by Defendants willfully and deliberately, and caused substantial financial injury to the consuming public and Plaintiffs.

86. As a direct and proximate result of the wanton and reckless actions and inactions of the Defendants as set forth above, Plaintiffs is entitled to punitive damages.

V. Prayer

WHEREFORE, PREMISES CONSIDERED, Plaintiffs pray that Defendants be cited to appear and answer herein and that upon the trial of this cause that Plaintiffs have judgment against Defendants for all of their damages as set out herein, pre-judgment interest at the highest legal rate allowed by law, post-judgment interest at the highest legal rate allowed by law, all costs of court, and for such other and further relief, both general and special, either at law or in equity, to which Plaintiffs may be justly entitled.

PLAINTIFFS DEMAND TRIAL BY JURY

COUNSEL FOR PLAINTIFFS

Respectfully submitted,

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